

103D CONGRESS
1ST SESSION

H. R. 2394

To amend the Public Health Service Act to establish programs of research with respect to women and cases of infection with the human immunodeficiency virus.

IN THE HOUSE OF REPRESENTATIVES

JUNE 10, 1993

Mrs. MORELLA (for herself, Mr. BIELENSON, Mr. FRANK of Massachusetts, Mr. FROST, Mr. GIBBONS, Mr. GILMAN, Mr. JEFFERSON, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. MATSUI, Mr. McDERMOTT, Mrs. MEEK, Mr. MILLER of California, Mrs. MINK, Ms. MOLINARI, Ms. NORTON, Mr. PAYNE of New Jersey, Mr. SANDERS, Mrs. SCHROEDER, Ms. SNOWE, Mr. STUDDS, Mr. TOWNS, Mrs. UNSOELD, Ms. WATERS, Mr. WHEAT, Mr. WYDEN, and Mr. YATES) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to establish programs of research with respect to women and cases of infection with the human immunodeficiency virus.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Women and AIDS Re-
5 search Initiative Amendments of 1993”.

1 **SEC. 2. ESTABLISHMENT OF GENERAL PROGRAM OF RE-**
2 **SEARCH REGARDING WOMEN AND ACQUIRED**
3 **IMMUNE DEFICIENCY SYNDROME.**

4 Part B of title XXIII of the Public Health Service
5 Act (42 U.S.C. 300cc-11 et seq.) is amended by adding
6 at the end the following section:

7 **“SEC. 2321. RESEARCH REGARDING WOMEN.**

8 “(a) IN GENERAL.—With respect to cases of infec-
9 tion with the human immunodeficiency virus, the Sec-
10 retary shall establish a program for the purpose of con-
11 ducting biomedical and behavioral research on such cases
12 in women, including research on the prevention of such
13 cases. The Secretary may conduct such research directly,
14 and may make grants to public and nonprofit private enti-
15 ties for the conduct of the research.

16 “(b) CERTAIN FORMS OF RESEARCH.—In carrying
17 out subsection (a), the Secretary shall provide for research
18 on—

19 “(1) the manner in which the human
20 immunodeficiency virus is transmitted to women, in-
21 cluding the relationship between cases of infection
22 with such virus and other cases of sexually transmit-
23 ted diseases, including clinical trials which examine
24 the question of how much human immunodeficiency
25 virus infection can be prevented by finding and
26 treating sexually transmitted diseases in women;

1 “(2) measures for the prevention of exposure to
2 and the transmission of such virus, including re-
3 search on—

4 “(A) the prevention of any sexually trans-
5 mitted disease that may facilitate the trans-
6 mission of the virus;

7 “(B) rapid, inexpensive, easy-to-use sexu-
8 ally transmitted disease diagnostic tests for
9 women;

10 “(C) inexpensive single dose therapy for
11 treatable sexually transmitted diseases;

12 “(D) the development of methods of pre-
13 vention for use by women; and

14 “(E) the development and dissemination of
15 prevention programs and materials whose pur-
16 pose is to reduce the incidence of substance
17 abuse among women;

18 “(3) the development and progression of symp-
19 toms resulting from infection with such virus, in-
20 cluding research regarding gynecological infections
21 as well as breast changes, hormonal changes, and
22 menses and menopause changes, whose occurrence
23 becomes probable as a result of the deterioration of
24 the immune system;

1 “(4) the treatment of cases of such infection,
2 including clinical research; and

3 “(5) behavioral research on the prevention of
4 such cases and research on model educational pro-
5 grams for such prevention.

6 “(c) CLINICAL TRIALS.—

7 “(1) GYNECOLOGICAL EVALUATIONS.—In clini-
8 cal trials regarding the human immunodeficiency
9 virus in which women participate as subjects, the
10 Secretary shall ensure that—

11 “(A) each female subject who is infected
12 with the human immunodeficiency virus—

13 “(i) undergoes a gynecological exam-
14 ination as part of the evaluation of the
15 medical status of the woman prior to par-
16 ticipation in the trial; and

17 “(ii) receives appropriate follow-up
18 services regarding such examination; and

19 “(B) the results of the gynecological ex-
20 aminations are analyzed to determine the rela-
21 tionship between gynecological conditions and
22 the infection with such virus.

23 “(2) STANDARD TREATMENTS FOR GYNECO-
24 LOGICAL CONDITIONS.—The Secretary shall conduct
25 or support clinical trials under subsection (a) to de-

1 termine whether standard methods of treating gyne-
2 cological conditions are effective in the case of such
3 conditions that arise as a result of infection with the
4 human immunodeficiency virus.

5 “(3) EFFECTIVENESS OF CERTAIN TREATMENT
6 PROTOCOLS.—With respect to cases of infection with
7 the human immunodeficiency virus, the Secretary
8 shall conduct or support clinical trials under sub-
9 section (a) to determine whether treatment protocols
10 approved for men with such cases are effective for
11 women with such cases.

12 “(4) SUPPORT SERVICES.—

13 “(A) In conducting or supporting clinical
14 trials regarding the human immunodeficiency
15 virus in which women participate as subjects,
16 the Secretary shall provide the women with
17 such transportation, child care, and other sup-
18 port services (including medical and mental
19 health services, treatment for drug abuse, and
20 social services, including services addressing do-
21 mestic violence) as may be necessary to enable
22 the women to participate as such subjects.

23 “(B) Services under subparagraph (A)
24 shall include services designed to respond to the
25 particular needs of women with respect to par-

1 ticipation in the clinical trials involved, includ-
2 ing, as appropriate, training of the individuals
3 who conduct the trials.

4 “(d) PREVENTION PROGRAMS.—

5 “(1) SEXUAL TRANSMISSION.—

6 “(A) With respect to preventing the sexual
7 transmission of the human immunodeficiency
8 virus, the Secretary shall conduct or support re-
9 search under subsection (a) on barrier methods
10 for prevention of sexually transmitted diseases,
11 including human immunodeficiency virus dis-
12 ease, that women can use without their sexual
13 partner’s cooperation or knowledge.

14 “(B) In carrying out subparagraph (A),
15 the Secretary shall give priority to identified re-
16 search needs and opportunities identified at the
17 National Institutes of Health sponsored meet-
18 ing on Development of Topical Microbicides
19 held in May 1993, including research on—

20 “(i) the early steps in infectious proc-
21 esses;

22 “(ii) identification, formulation, and
23 preclinical evaluation of new preparations;

24 “(iii) clinical testing for safety and ef-
25 ficacy; and

1 “(iv) studies on acceptability and com-
2 pliance of safe, effective microbicides.

3 “(2) EPIDEMIOLOGICAL RESEARCH.—The Sec-
4 retary shall conduct or support epidemiological re-
5 search under subsection (a) to determine the factors
6 of risk regarding infection with the human
7 immunodeficiency virus that are particular to
8 women, including research regarding—

9 “(A) the use of various contraceptive meth-
10 ods;

11 “(B) the use of tampons;

12 “(C) the relationship between such infec-
13 tion and other sexually transmitted diseases;

14 “(D) the relationship between such infec-
15 tion and various forms of substance abuse (in-
16 cluding use of the form of cocaine commonly
17 known as crack); and

18 “(E) the relationship between such infec-
19 tion and noncoital forms of sexual activity.

20 “(e) INTERAGENCY STUDY.—With respect to the
21 study (known as the Women’s Interagency HIV Study)
22 that, as of June 1993, is being carried out by the Sec-
23 retary through various agencies of the Public Health Serv-
24 ice for the purpose of monitoring the progression in
25 women of infection with the human immunodeficiency

1 virus, and determining whether such progression is dif-
2 ferent in women than in men, the following applies:

3 “(1) The Secretary shall ensure that not less
4 than 5,000 women with such infection are included
5 in the study.

6 “(2) The Secretary shall provide for an increase
7 in the number of sites at which the study is to be
8 conducted.

9 “(3) The Secretary shall ensure that the study
10 period is for a minimum of 8 years.

11 “(4) With respect to markers of human
12 immunodeficiency virus disease progression and viral
13 activity, including the cells commonly known as CD4
14 cells, the Secretary shall ensure that the study ade-
15 quately addresses the relationship between such
16 markers and the development of serious illnesses in
17 such women, including the relationship between the
18 number of such cells and the development of such
19 illnesses. For purposes of the preceding sentence,
20 the study shall address gynecological conditions, and
21 other conditions particular to women, that are not
22 currently included in the list of conditions arising
23 from such infection that, for surveillance purposes,
24 is maintained by the Director of the Centers for Dis-
25 ease Control and Prevention.

1 “(f) DEFINITIONS.—For purposes of this section, the
2 term ‘human immunodeficiency virus’ means the etiologic
3 agent for acquired immune deficiency syndrome.

4 “(g) AUTHORIZATIONS OF APPROPRIATIONS.—

5 “(1) CLINICAL TRIALS.—

6 “(A) For the purpose of carrying out sub-
7 section (c)(1), there are authorized to be appro-
8 priated \$20,000,000 for fiscal year 1994, and
9 such sums as may be necessary for each of the
10 fiscal years 1995 through 1996.

11 “(B) For the purpose of carrying out sub-
12 section (c)(2), there are authorized to be appro-
13 priated \$10,000,000 for fiscal year 1994, and
14 such sums as may be necessary for each of the
15 fiscal years 1995 through 1996.

16 “(C) For the purpose of carrying out sub-
17 section (c)(3), there are authorized to be appro-
18 priated \$10,000,000 for fiscal year 1994, and
19 such sums as may be necessary for each of the
20 fiscal years 1995 through 1996.

21 “(D) For the purpose of carrying out sub-
22 section (c)(4), there are authorized to be appro-
23 priated \$15,000,000 for fiscal year 1994, and
24 such sums as may be necessary for each of the
25 fiscal years 1995 and 1996.

1 “(2) PREVENTION PROGRAMS.—

2 “(A) For the purpose of carrying out sub-
3 section (d)(1), there are authorized to be appro-
4 priated \$30,000,000 for fiscal year 1994, and
5 such sums as may be necessary for each of the
6 fiscal years 1995 through 1996.

7 “(B) For the purpose of carrying out sub-
8 section (d)(2), there are authorized to be appro-
9 priated \$10,000,000 for fiscal year 1994, and
10 such sums as may be necessary for each of the
11 fiscal years 1995 through 1996.

12 “(3) INTERAGENCY STUDY.—For the purpose
13 of carrying out subsection (e), there are authorized
14 to be appropriated \$15,000,000 for fiscal year 1994,
15 and such sums as may be necessary for each of the
16 fiscal years 1995 through 1996.”.

○